Opening Statement of Chairman Greg Walden
Subcommittee on Health
Hearing on "Examining FDA's Medical Device User Fee Program"
March 28, 2017

(As prepared for delivery)

The last time Congress reauthorized the Medical Device User Fee Amendments (MDUFA) in 2012, we heard story after story about venture capital drying up and innovative medical technology companies launching their products overseas, oftentimes years before American patients could benefit from them. Witnesses from all sides of the political spectrum came before this subcommittee and highlighted the burdensome, inconsistent, and opaque nature of the FDA review process as the primary driver of these alarming trends.

What a difference five years makes.

Thanks to Dr. Burgess and others, the Food and Drug Administration Safety and Innovation Act (FDASIA) included a number of common-sense regulatory improvements that greatly benefitted patients and spurred innovation.

I would like to specifically thank Dr. Jeff Shuren, who is here with us today, for his leadership. All of the legislation in the world could not change the deeply rooted cultural issues that were plaguing the device center at FDA. Dr. Shuren took constructive feedback to heart and put these new legislative authorities to work.

Since 2009, the number of innovative devices approved by the FDA has almost quadrupled, resulting in American patients benefiting from safe and effective American technologies sooner. In 2009, it took an average of 427 days before FDA even reached a decision on a premarket approval application (PMA). As of 2015, the average review time was down to 276 days—a 35 percent decrease. More work lies ahead, but great strides have been made.

Building upon the successful implementation of the previous user fee agreement, 21st Century Cures also included a number of additional bipartisan process reforms. Reauthorizing MDUFA in a timely fashion—which I remain steadfastly committed to doing—will ensure that we continue to move in the right direction. Today's hearing continues these efforts.

This is a good agreement that will build upon some recent successes and strengthen the agency, improve the lives of patients, and bolster America's medical technology sector which has brought hundreds of thousands of high-paying jobs to our communities. It's also a critical next step after the game-changing 21st Century Cures Act became law just a few months ago. Let's continue to build upon these remarkable advancements and put patients first.